

REMARKS

This application is amended in a manner to place it in condition for allowance.

**Status of the Claims**

Claims 23-25, 28-42, 44-72 are cancelled, without prejudice.

Claims 73-76, 79 and 80 remain pending in the application.

**Claim Rejections under 35 USC §103(a)**

Claims 73-74 and 75-80 were separately rejected under 35 USC §103(a) as being unpatentable over LANGFORD US 5,906,802 ("LANGFORD") in view of WALDMANN-LAUE et al. US 5,539,001 ("WALDMANN-LAUE") and TU et al. WO 92/09309 ("TU"). These rejections are respectfully traversed for the reasons below.

An endoscope is a thermolabile instrument, which loses its properties at a certain temperature. Solutions previously used for thermochemical disinfection damaged endoscopes, e.g., by corrosion of the surface materials, at the temperatures necessary for disinfection. See, e.g., the discussion at page 2 of the present specification lines 20-35.

Independent claim 73, however, is directed to a process, where the thermal disinfection of a flexible endoscope is carried out at a temperature from about 90°C to about 100°C.

LANGFORD was offered for teaching endoscope sterilization, but LANGFORD fails to disclose a disinfection time, temperature of the sterilant, the amount of contamination present and the use of an alkyl glycol ether.

WALDMANN-LAUE was offered for teaching low-temperature disinfection with an aromatic alcohol and glycerol ether having a C<sub>6-22</sub> alkoxyethyl group, as well as an initial cleaning step.

TU was offered for the following:

Tu et al. teaches a method of sterilization of thermolabile hard surfaces using a mixture of a glycidyl ether and an aromatic alcohol. Tu et al. further discloses that the "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time." For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-54. Thus, it would have been obvious to increase and optimize the treatment temperature, an established result effective variables, based upon the particular concentration of sterilant used and the amount of contamination present, to both increase the percent kill and to reduce the treatment time.

However, neither the recited time nor the recited temperature is suggested by TU for disinfecting flexible endoscopes at from about 90°C to about 100°C for from about 1 to about 20 minutes, let alone disinfecting any thermolabile surface from about 90°C to about 100°C for any given time period.

As to the time for sterilization, TU discloses:

" Generally, however, the sterilization time needed to reduce the population of microorganism by 90 percent ranges from about 5 to 120 hours, preferably 4 to 60 hours." See, e.g., page 8, lines 4-14.

Accordingly, TU suggests that sterilization requires at least 4 hours.

As to the particular temperature selected, TU discloses two types of device. TU discloses implantable biological devices are destroyed by high temperature, i.e., "thermolabile" devices. See, e.g., page 2, lines 10-14. TU also disclose on-biological items, such as surgical instruments and medical devices, e.g., on page 4 lines 15-19.

However, TU does not sterilize the surfaces of these devices at the same temperature:

"Generally the temperature of the solution is maintained in the range from room temperature to about 100 degrees C. for surgical instruments or medical devices in general, but for biological devices the preferred temperature range is from about 20 (room temperature) to about 45 degrees C. to avoid damage to the tissue." See, e.g., page 7, lines 29-35(Emphasis Added.)

Thus, as thermolabile surfaces of TU are limited to sterilizing temperatures of no more than about 45°C and flexible endoscopes are thermolabile instruments, one of ordinary skill in the art to would have been dissuaded to increase the temperature of disinfection in LANGFORD. It would have been unobvious to combine a method of disinfecting a flexible endoscope and a temperature of disinfection in a range of from about 90°C to about 100°C, or select any particular time for disinfecting in that temperature range.

Therefore, withdrawal of the rejection is respectfully requested.

**Claim Rejections under Double Patenting**

Claims 73-81 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting being unpatentable over claims 67-73, 75 and 80 of Application No. 10/825,266. This rejection is respectfully traversed.

Independent claim 73 of the present application is directed to a process, which includes disinfecting a flexible endoscope at a temperature from about 90°C to about 100°C.

Claims 67-73, 75 and 80 of the cited Application, however, are not directed to an endoscope. As discussed above relative to the obviousness rejection, an endoscope is a thermolabile instrument, which loses its properties at a certain temperature. Solutions previously used for thermochemical disinfection were known to damage endoscopes at the temperatures necessary for disinfection.

Thus, the known thermolabile characteristic of flexible endoscopes, would have dissuaded one of ordinary skill in the art to increase the temperature of disinfection, as evidenced by the sections of TU discussed above relative to the obviousness rejection, e.g., thermolabile devices may not be heated to the same elevated temperatures as non-thermolabile devices.

Therefore, withdrawal of the rejection is respectfully requested.

**Conclusion**

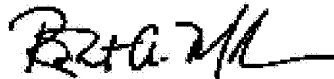
In view of the cancelled claims, and the foregoing remarks, the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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